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Ministerie van Volksgezondheid, Welzijn en Sport
Directie Geneesmiddelen en Medische Technologie

5.1.2e

Datum 18 oktober 2023
Ons kenmerk 5.1.2e
Betreft Overleg Herziening Europese geneesmiddelenwetgeving

Geachte 5.1.2e

Naar aanleiding van ons overleg op 17 oktober jl. over de herziening van de Europese geneesmiddelenwetgeving sturen we een samenvatting van de besproken onderwerpen. De KNMP wil u nogmaals danken voor de gelegenheid om te reageren op het voorstel voor de herziening van de Europese regelgeving voor geneesmiddelen.

We hebben met interesse kennisgenomen van het voorstel Reform of the EU pharmaceutical legislation (europa.eu) (hierna: het voorstel). De Europese farmawetgeving schept immers een aantal randvoorwaarden, zodat apotheker hun werk goed kunnen doen. Apothekers dragen door goede farmaceutische zorg bij aan de behandeling en genezing van patiënten en preventie. Zij doen dit in goede samenwerking met andere zorgverleners in de eerste en tweedelijnszorg. In deze brief zet KNMP de opmerkingen over het voorstel uiteen. Gegroepeerd in vier thema's:

1. Verbeter de beschikbaarheid van geneesmiddelen
2. Versterk de zorgfunctie van de apotheek en apotheker
3. Zorg voor een duurzaam en toekomstbestendig verzekerd geneesmiddelenpakket
4. Optimaliseer gegevensuitwisseling en digitalisering in de zorg

1. Verbeter de beschikbaarheid van geneesmiddelen

buiten verzoek

a) Tijdslijn

b) Interventies door apothekers

Creëer werkbare oplossingen voor apothekers bij de omgang met tekorten. Daarvoor stellen we het volgende voor: maak het mogelijk dat de omzetting naar een alternatief geneesmiddel zonder nieuw recept van de voorschrijver, sneller en vaker tekortenbesluiten of een alternatieve oplossing voor import zonder tekortenbesluit, uitwisseling van voorraden tussen de openbare apotheken en de ziekenhuisapotheken, en het toestaan om apotheekbereidingen door te leveren. Momenteel is het nu verboden (Geneesmiddelenwet) om voorraden tussen apotheken uit te wisselen en het zou kunnen helpen wanneer daarvoor ruimte zou worden gecreëerd, waardoor zowel extra- als intramurale patiënten langer kunnen worden geholpen.

c) Apotheekbereidingen

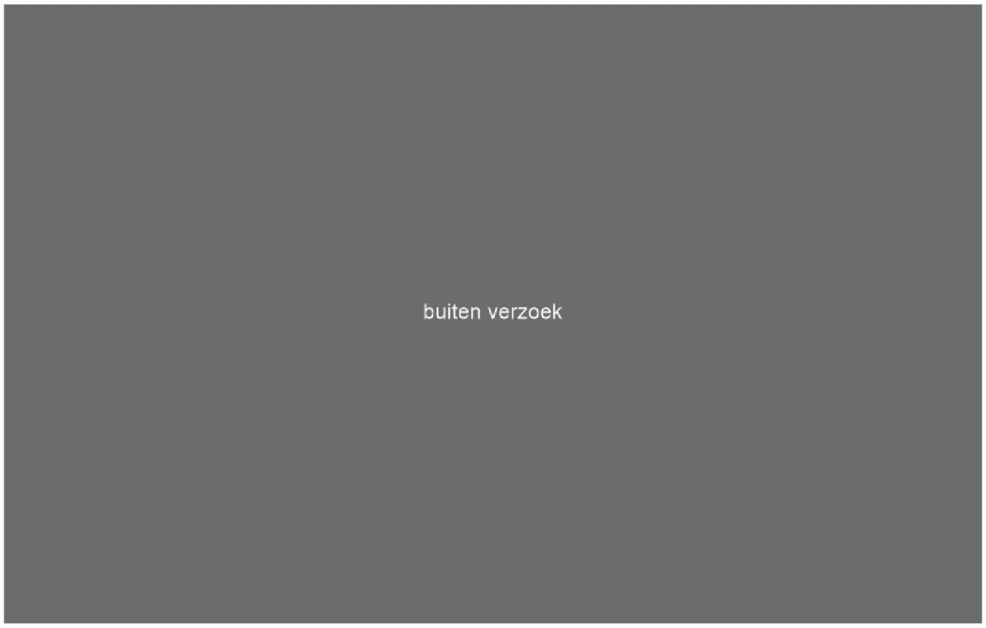
Jaarlijks zijn circa 2,5 miljoen Nederlanders afhankelijk van een apotheekbereiding. Hierbij gaat het om zo'n 7,5 miljoen apotheekbereidingen in de openbare apotheek. Apothekers maken al decennialang geneesmiddelen op maat voor hun patiënten (personalised medicine) en zijn de enige beroepsgroep met de expertise én de wettelijke bevoegdheid om geneesmiddelen te bereiden voor eigen patiënten (of in kleinschalige collegiale samenwerking), ook als er een patent op rust.

Als geneesmiddelen niet beschikbaar zijn als gevolg van een tijdelijk tekort of ontbreken van een geschikt geregistreerd geneesmiddel, kunnen apothekers door het zelf bereiden van geneesmiddelen in hun apotheek daarin een rol spelen. Onder apotheekbereidingen verstaan we hier twee organisatievormen van het bereiden: doorgeleverde bereidingen van grootbereiders en de magistrale bereidingen op kleine schaal van apothekers die in hun eigen apotheek voor eigen patiënten bereiden. Omdat niet elke apotheker magistrale bereidingen produceert in zijn apotheek is deze vaak afhankelijk van een doorgeleverde bereiding van een bereidende collega. Daarbij dient het collegiaal doorleveren door apothekers onder voorwaarden, (zoals er is geen geregistreerd adequaat alternatief beschikbaar in een land, productie voldoet aan de Good Manufacturing Practices (GMP), etc.), te gebeuren. Doorgeleverde bereidingen moeten bij tekorten administratief en juridisch makkelijker toegelaten worden. Met de huidige wet- en regelgeving zitten we aan de grenzen van de beroepsuitoefening.

In het voorstel is het een gemiste kans om de doorgeleverde bereidingen in art 1 lid 5 juridisch Europees te verankeren door deze niet als uitzondering op te nemen in de Europese geneesmiddelenwetgeving.

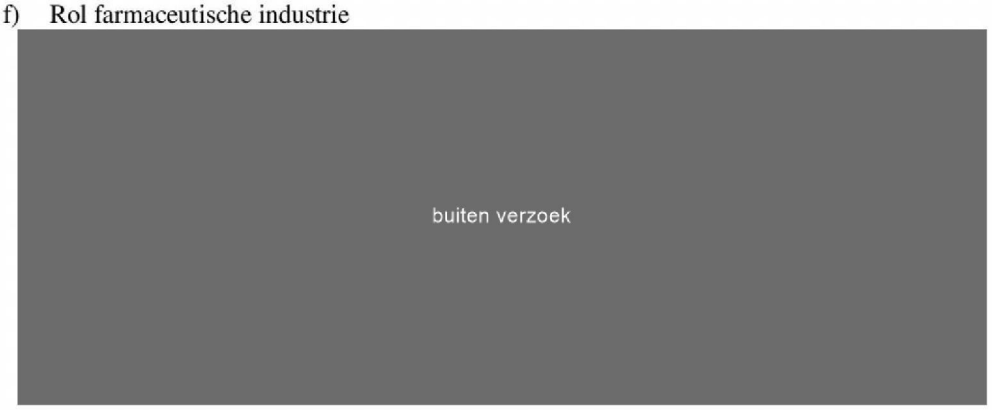
In de huidige en herziende Europese regelgeving voor geneesmiddelen blijft de mogelijkheid gehandhaafd om magistrale bereidingen op het huidige niveau in openbare apotheken en ziekenhuisapotheken uit te voeren.

d) EMA



e) Communicatie

f) Rol farmaceutische industrie



2. Versterk de zorgfunctie van de apotheek en apotheker

buiten verzoek

KNMP

3. Zorg voor een duurzaam en toekomstbestendig verzekerd geneesmiddelenpakket

4. Optimaliseer gegevensuitwisseling en digitalisering in de zorg

Amendementen
In de bijlage is de lijst met amendementen toegevoegd. Een deel van deze amendementen hebben we besproken in ons overleg en is uitgelicht in deze brief.

Met vriendelijke groet,

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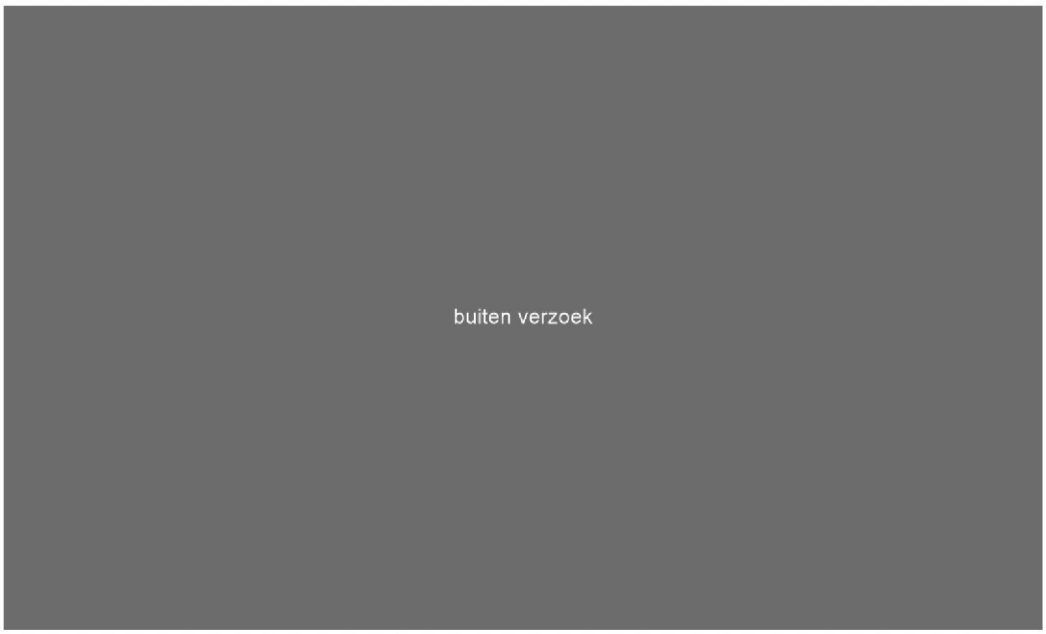
BIJLAGE: Amendementen

BIJLAGE Voorstel van AMENDEMENTEN van de KNMP

Proposal for a Directive on the Union code relating to medicinal products for human use

Article 1 – paragraph 2

Text proposed by the Commission	**Amendment**
2. This Directive shall apply to medicinal products for human use intended to be placed on the market.	2. This Directive shall apply to medicinal products for human use intended to be placed on the market **in Member States and either prepared industrially or manufactured by a method involving an industrial process.**
Justification	
The existing wording of the Directive should be maintained as there is no justification given for this deletion, which could limit the ability of pharmacists to compound medicines for the benefit of patients. Given the intention of maintaining the scope as it is, per Recital 12, and the absence of an analysis of the implications on compounding by pharmacists within the impact assessment, it appears that this is an unintended consequence of this amendment and that the gravity of the change was not appreciated. Pharmaceutical compounding by community and hospital pharmacists must be preserved and further promoted at national level as a solution for unmet medical needs of small populations as well as shortages of medicinal products for which there are no suitable alternatives available on the market. A number of national regimes exist which permit pharmacy compounding which falls below the threshold of being 'industrial' in nature or involving an 'industrial process' in addition to the magistral and officinal formulae exemptions. There is no analysis in the impact assessment to suggest that such regimes, which have been in place now for over two decades, present any shortcomings – particularly in light of the benefits of addressing unmet medical needs and shortages. As such, a clear, evidence-based justification must be given to support the decision to now include within scope all medicinal products regardless of their method of preparation and a clear carve-out is needed to ensure that pharmacies remain exempted where they compound using non-industrial processes.	



Article 17

Text proposed by the Commission	**Amendment**
1. Where the application for a marketing authorisation concerns an antimicrobial, the application shall, in addition to the information referred to in Article 6, contain the following: (a) an antimicrobial **stewardship** plan as referred to in Annex I; (b) a description of the special information requirements outlined in Article 69 and listed in Annex I. 2. The competent authority may impose obligations on the marketing authorisation holder if it finds the risk mitigation measures contained in the antimicrobial **stewardship** plan unsatisfactory.	1. Where the application for a marketing authorisation concerns an antimicrobial, the application shall, in addition to the information referred to in Article 6, contain the following: (a) an antimicrobial **resistance mitigation** plan as referred to in Annex I; (b) a description of the special information requirements outlined in Article 69 and listed in Annex I. 2. The competent authority may impose obligations on the marketing authorisation holder if it finds the risk mitigation measures contained in the antimicrobial **resistance mitigation** plan unsatisfactory.
Justification	
Antibiotic stewardship is not the right term for what is expected from the marketing authorization holders in relation to approved antimicrobials. As defined in the European Commission's guidelines of prudent use of antimicrobials, antimicrobial stewardship is an organisational or healthcare system-wide approach to promoting and monitoring judicious use of antimicrobials to preserve their future effectiveness. Activities to be taken solely by the pharmaceutical company should not be called antimicrobial stewardship, as this term is reserved for a broader and systemic actions to be taken by health systems and healthcare professionals.	

Article 17 – paragraph 3

Text proposed by the Commission	**Amendment**
3. The marketing authorisation holder shall ensure that the pack size of the antimicrobial corresponds to the usual posology and duration of treatment.	3. **The marketing authorisation holder shall ensure, wherever possible, that the antimicrobial may be dispensed per unit in a number corresponding to the quantities described on the prescription. If an antimicrobial can not be dispensed per unit** the marketing authorization holder shall ensure that the pack size of the antimicrobial corresponds to the usual posology and duration of treatment
Justification	
Per unit dispensing of antimicrobials has been listed as a core component of prudent use of antimicrobials in the EU guidelines. As the actual size of packaging of antimicrobials is difficult to adjust to all clinical guidelines, which may also change over time, the best way to dispense the needed quantity and to avoid stocking and waste is to dispense the exact number of units needed. The proposed provision on adjusting the package size to the usual posology and duration of the treatment is a step in the right direction, however per unit dispensing is more ambitious measure to limit the spread of AMR.	

Article 51 – paragraph 1 – point (e)

Text proposed by the Commission	**Amendment**
(e) is an antimicrobial; or	(e) is an antibiotic ***for systemic use***; or
Justification	
This new provision is targeted at limiting antimicrobial resistance, as it introduces a requirement, in European Law, for a prescription for all antimicrobials (defined previously as any antibiotic, antiviral, or antifungal). This impacts pharmacy practice as Member States have some antimicrobial products available at the pharmacy without the need for a prescription, for example topical antivirals for labial herpesvirus infections. Furthermore, Member States have implemented protocol-based dispensing for some antimicrobials, making them available at the pharmacy without the need for a doctor visit, especially in time-sensitive conditions (e.g. uncomplicated urinary tract infections) and/or following a rapid diagnostic test for screening of bacterial infections. Member States are encouraged to introduce restrictions to the use of antimicrobials: for example, by implementing testing services at the community pharmacy level to confirm bacterial infections (per Recital 68). With this amendment, it is proposed that only systemic antibiotics are subject to mandatory medical prescription, given its safety profile and prudent use in order to fight antimicrobial resistance. Finally, such a far-reaching provision could gravely impact the financial resources of health funds in the Member States (additional reimbursement of doctors' treatment and for the medicines prescribed).	

Article 51 – paragraph 2

Text proposed by the Commission	**Amendment**
3. Member States may set additional conditions on the prescription of antimicrobials, restrict the validity of medical prescription **and limit the quantities prescribed to the amount required for the treatment or therapy concerned or submitting** certain antimicrobial medicinal products to special medical prescription or restricted prescription.	3. Member States may set additional conditions on the prescription of antimicrobials, restrict the validity of medical prescription **or submit** certain antimicrobial medicinal products to special medical prescription or restricted prescription. **3a. (new) Wherever possible, Member States shall provide that prescriptions and dispensation shall be aligned with the number of units** required for the treatment or therapy concerned.
Justification	
Per-unit dispensing of antimicrobials has been listed as a core component of prudent use of antimicrobials in the EU guidelines. As the actual size of packaging of antimicrobials is difficult to adjust to all clinical guidelines, which may also change over time, the best way to dispense the needed quantity and to avoid stocking and waste is to dispense the exact number of units needed. The proposed provision on adjusting the package size to the usual posology and duration of the treatment is a step in the right direction, however per-unit dispensing is more ambitious measure to limit the spread of AMR.	

Article 56 – paragraph 1 (new)

Text proposed by the Commission	Amendment
	The marketing authorisation holder shall, in good faith, file for pricing and reimbursement in the Member States in which the marketing authorisation is valid within 4 months months after the marketing authorisation was granted. The marketing authorisation holder shall be exempt from this obligation provided the competent authority of the Member State grants a product specific waiver. The obligation referred to in the first subparagraph shall exclude medicinal products defined in Article 4.1 (13), Article 10, Article 11, Article 12. Member States representatives may request the Commission to discuss issues related to this obligation in the Committee established by Council Decision 75/320/EEC ("Pharmaceutical Committee). The Commission might invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.

Justification

Proposed incentive for launch in all Member States concerned does focus on the end results – availability of medicines – but at the same time the extension of regulatory data protection applies only to approx. 30% of medicines (where the RDP is the last period of regulatory protection). CPME welcomes this attempt to improve availability of medicines, however we believe that an obligation for all marketing authorisation holders to file for pricing and reimbursement, in good faith, will result in broader coverage of medicines and will push manufacturers and the Member States to negotiate fair prices and ensure availability of medicines.

Proposed obligation does not cover generic and biosimilar medicinal products. This amendment results in deleting provisions related to 24 months extension of regulatory data protection.

Article 56 – paragraph 3

Text proposed by the Commission	**Amendment**
3. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall**, within the limits of its responsibility,** ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies **or** persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered. The arrangements for implementing the first subparagraph should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.	3. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies ***and*** persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered. The arrangements for implementing the first subparagraph should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.
Justification	
The current proposed wording does not ensure marketing authorisation holders are obliged to supply all relevant supply chain actors mentioned in the proposed text. In the Commission wording it could be understood as marketing authorisation holders fulfilling the supply duties to the different actors as if they were alternative, whereas adequate supply must be guaranteed to all of these actors (wholesale distributors, pharmacies and persons authorised under national law to supply medicinal products to the public). Changing the preposition would guarantee that marketing authorisation holders ensure appropriate supply to all actors in the medicine supply chain, leading to a continuous supply to the population through all supply channels available in a Member State (this being one of the main objectives of the amendment to ensure continuity of supply), thus ensuring that a fairer distribution of medicines to the various actors, adapted to the population's health needs. The term “within the limits of its responsibility” is not clear and does not provide sufficient accountability of the marketing authorisation holders. It is common knowledge that many reasons for medicine shortages lay on the side of the marketing authorisation holder. It is therefore essential to either clarify those limits or to remove them from the legislation	

Article 57

Text proposed by the Commission	**Amendment**
1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support. Within 30 days after the marketing authorisation is granted the marketing authorisation holder shall: (a) draw up an electronic report listing: (i) the amount of financial support received and the date thereof; (ii) the public authority or publicly funded body that provided the financial support referred to in point (i); (iii) the legal entity that received the support referred to in point (i)	1. The marketing authorisation holder shall declare to the public any direct financial support **and indirect financial benefits** received from any public authority or publicly funded body, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support. Within 30 days after the marketing authorisation is granted the marketing authorisation holder shall: (a) draw up an electronic report listing: (i) the amount of financial support received and the date thereof; (ii) the public authority or publicly funded body that provided the financial support referred to in point (i); (iii) the legal entity that received the support referred to in point (i) **(iv) the percentage of total research and development costs of the medicinal product covered by the support referred to in point (i).**
Justification	
It should be a requirement that the R&D costs of medicinal products that have benefited from public funding are transparent and include minimum information on the breakdown between private and public investment. This would empower national authorities by reducing information asymmetry in pricing negotiations, enable informed discussion on what constitutes a fair price for these medicines and allow public accountability for the use of public resources. It is important to know the ratio of the public and private investments, to know the scale of public support, which often is higher than claimed	

Article 63 – paragraph 3

Text proposed by the Commission	**Amendment**
3. Member States ***may decide*** that the package leaflet shall be made available in paper format ***or*** electronically***, or both. In the absence of such specific rules in a Member State, a*** package leaflet in paper format ***shall be*** included in the packaging of a medicinal product***. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.***	3. Member States ***shall ensure*** that the package leaflet shall be made available in paper format ***and*** electronically. ***The marketing authorisation holder shall ensure that the*** package leaflet in paper format ***is*** included in the packaging of a medicinal product.
Justification	
It is crucial that a paper version is always available for the patient, recognising that the leaflet is key for patient safety and that not all European citizens have easy access to digital means by which to access such crucial information. Current legislation already foresees that national competent authorities and the Agency provide an electronic version of package leaflet by means of the European and national medicines web-portal. Ensuring that a paper version of the patient information leaflet is supported and complemented by its digital version respects the different literacy levels on health and digital fields in the various Member States. Furthermore, the burden of providing paper-form leaflets must not fall to community pharmacists to fund and operationalise, considering that it is the responsibility of the marketing authorisation holder to supply this information to patients. Little or no attention has been given to the cost and time associated with printing individual paper leaflets at the community pharmacy, while risks to the patient in the event of a misprint may undermine the paramount concern of patient safety.	

Article 63 – paragraph 5

Text proposed by the Commission	Amendment
5. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version of the package leaflet. That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request and free of charge. The delegation of powers shall apply as of [OP please insert the date = five years following 18 months after the date of entering into force of this Directive].	Delete
Justification	
It is crucial that a paper version is always available for the patient, recognising that the leaflet is key for patient safety and that not all European citizens have easy access to digital means by which to access such crucial information. Furthermore, the burden of providing paper-form leaflets must not fall to community pharmacists to fund and operationalise but rather must be borne by the marketing authorisation holder. Little or no attention has been given to the cost and time associated with printing individual paper leaflets at the community pharmacy, while risks to the patient in the event of a misprint may undermine the paramount concern of patient safety.	

Article 63 – paragraph 6

Text proposed by the Commission	Amendment
6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.	6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies. ***The Commission shall consult with the European Data Protection Supervisor and the Agency in this process.***
Justification	
Patient privacy is of paramount importance in the design of any technology giving access to medicines information. Therefore, any existing or developing technology that allows access for patient information should comply with the European standards on data protection and the relevant bodies should be involved in this process.	

Article 63 – paragraph 7

Text proposed by the Commission	**Amendment**
7. Where the package leaflet is made available electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes.	7. Where the package leaflet is made available electronically, the individual right to privacy shall be ensured***, in line with Regulation (EU) 2016/679 and Directive 2002/58/EC***. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes, ***including advertising and marketing activities.***
Justification	
Patient privacy is of paramount importance in the design of any technology giving access to medicines information. Therefore, any existing or developing technology that allows access for patient information should comply with the European standards on data protection. Furthermore, any technology should not allow patient identification, profiling or targeting for advertising or marketing purposes.	

Article 63 – paragraph 8 (new)

Text proposed by the Commission	**Amendment**
	8. The competent authority of the Member State or, where appropriate, the Agency, shall have the oversight of the technology giving access the electronic version of package leaflet, guaranteeing compliance with paragraph 7. The competent authority of the Member State shall decide the means of storage and access to the electronic version of the package leaflet that shall be made available by the national medicines web-portals and the European medicines web-portal according to Article 102 (1).
Justification	
Electronic product information shall be exempt from any commercial information, provide unbiased and science-based information. Therefore, National Competent Authorities and/or the European Medicines Agency shall have oversight of the technology that provides access to the electronic version of the package leaflet. Furthermore, this information shall be stored and be accessed through means defined by the National Competent Authorities and/or the European Medicines Agency. Article 102 (1) (b) already contains the requirement for package leaflets to be published in the regulatory web-portals; a cross-reference to this Article provides better transparency.	

Article 67 – paragraph 6

Text proposed by the Commission	**Amendment**
6. Member States may, for the purposes of reimbursement, pharmacovigilance, pharmacoepidemiology **or for data protection prolongation for market launch** use the information contained in the repositories system referred to paragraph 2, second subparagraph, point (e).	6. Member States may, for the purposes of reimbursement, pharmacovigilance, pharmacoepidemiology use the information contained in the repositories system referred to paragraph 2, second subparagraph, point(e).
Justification	
Despite Recital 4 stating that the provisions on falsified medicines are maintained, the European Commission proposes an additional use for the repository systems created in the context of the European Medicines Verification System (EMVS). The Delegated Regulation (EU) 2016/161, which sets up the EMVS, pays special attention to the uses that can be made of the data generated and recorded in the repositories, in order to guarantee their protection. Recital 37 of this Regulation clearly states it is necessary to ensure the protection of the legitimate interests to protect information of a commercially confidential nature and the ownership and confidentiality of the data generated by the use of the safety features, and for that reason manufacturers, marketing authorisation holders, wholesalers and persons authorised or entitled to supply medicinal products to the public should only have ownership of and access to the data they generate when they interact with the repositories system. The new proposed use of EMVS that is introduced in this provision for the purpose of verifying market launch is concerning, not only because of the above considerations, but also because it is built on the assumption that the upload of unique identifiers translates to the actual supply of the market, which is not the reality. Furthermore, the EMVS does not cover all medicines marketed. Due to all of these concerns, we suggest that the additional limitation referred to above should not be introduced and Member States should seek other means to verify the marketing status for the purpose of data protection, namely on the basis of article 56 paragraphs 2 and 9 of the proposed Directive.	

Article 69

Text proposed by the Commission	**Amendment**
The marketing authorisation holder **shall** ensure availability of **educational** material to healthcare professionals, **including through medical sales representatives as referred to in Article 175(1), point (c),** regarding the appropriate use of diagnostic tools, testing or other diagnostic approaches related to antimicrobial-resistant pathogens, that may inform on the use of the antimicrobial.	**In case of absence of appropriate guideline ,** the marketing authorisation holder **may** ensure availability of **informational** material to healthcare professionals, regarding the appropriate use of diagnostic tools, testing or other diagnostic approaches related to antimicrobial-resistant pathogens, that may inform on the use of the antimicrobial. **The informational material referred to in the first paragraph shall be compatible with the summary of product characteristics.** **Materials referred to in the first subparagraph shall not constitute advertising referred to in Chapter XIII.**
Justification	
The best source of information on the use of diagnostics tools are the official guidelines. Only in cases, where such guidelines do not exist, marketing authorisation holders may provide information to healthcare professionals. The medical sales representatives are not the right way to provide this information to healthcare professionals. It must be ensured that the information on appropriate use of the diagnostic tools is compatible with the summary of products characteristics and does not involve advertising.	

Article 69 – paragraph 2

Text proposed by the Commission	**Amendment**
2. The marketing authorisation holder shall include in the packaging of antimicrobials a document that contains specific information about the medicinal product concerned and that is made available to the patient in addition to the product leaflet ("awareness card") with information on antimicrobial resistance and the appropriate use and disposal of antimicrobials. **Member States may decide that** the awareness card shall be made available in paper format **or** electronically**, or both**. In the absence of such specific rules in a Member State, an awareness card in paper format shall be included in the packaging of an antimicrobial.	2. The marketing authorisation holder shall include in the packaging of antimicrobials a document that contains specific information about the medicinal product concerned and that is made available to the patient in addition to the product leaflet ("awareness card") with information on antimicrobial resistance and the appropriate use and disposal of antimicrobials. The awareness card shall be made available in paper format **and** electronically. In the absence of such specific rules in a Member State, an awareness card in paper format shall be included in the packaging of an antimicrobial.
Justification	
Ensuring that AMR awareness information is accessible to all, and in particular to patients/consumers with diverse abilities, is essential, and therefore the AMR awareness card with information on antimicrobial resistance and disposal shall be accessible in paper format as well. Same rule should apply to package leaflet (Article 63 Directive).	

Article 81 – paragraph 2 (a)

Text proposed by the Commission	Amendment
24 months, where the marketing authorisation holder demonstrates that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was granted or, within three years from that date for any of the following entities: **(i) SMEs within the meaning of Commission Recommendation 2003/361/EC;** **(ii) entities not engaged in an economic activity ('not-for-profit entity'); and** **(iii) undertakings that, by the time of granting of a marketing authorisation, have received not more than five centralised marketing authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest**	Delete

Justification

Proposed incentive for launch in all Member States concerned does focus on the end results – availability of medicines – but at the same time the extension of regulatory data protection applies only to approx. 30% of medicines (where the RDP is the last period of regulatory protection). CPME welcomes this attempt to improve availability of medicines, however we believe that an obligation for all marketing authorisation holders to file for pricing and reimbursement, in good faith, will result in broader coverage of medicines and will push manufacturers and the Member States to negotiate fair prices and ensure availability of medicines. Proposed obligation does not cover generic and biosimilar medicinal products. This amendment results in deleting provisions related to 24 months extension of regulatory data protection.

Article 82

Text proposed by the Commission	Amendment
Prolongation of the data protection period for medicinal products supplied in Member States **1. The prolongation of the data protection period referred to in Article 81(2), first subparagraph, point (a), shall only be granted to medicinal products if they are released and continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorisation is valid.** **The prolongation referred to in the first subparagraph shall apply to medicinal products that have been granted a centralised marketing authorisation, as referred to in Article 5 or that have been granted a national marketing authorisation through the decentralised procedure, as referred to in Chapter III, Section 3.** **2. To receive a prolongation referred to in Article 81(2), first subparagraph, point (a), the marketing authorisation holder shall apply for a variation of the relevant marketing authorisation. The application for a variation shall be submitted between 34 and 36 months after the date when the initial marketing authorisation was granted, or for entities referred to in Article 81(2), first subparagraph, point (a), between 46 and 48 months, after that date. The application for a variation shall contain documentation from the Member States in which the marketing authorisation is valid. Such documentation shall:** **(a) confirm that the conditions set out in paragraph 1 have been satisfied in their territory; or** **(b) (b)waive the conditions set out in paragraph 1 in their territory for the purpose of the prolongation. Positive decisions adopted in accordance with Articles 2 and 6 of Council Directive 89/105/EEC 74 shall be considered equivalent to a**	Delete

confirmation referred to in the third subparagraph, point (a). **3. To receive the documentation referred to in paragraph 2, third subparagraph, the marketing authorisation holder shall make a request to the relevant Member State. Within 60 days from the request of the marketing authorisation holder, the Member State shall issue a confirmation of compliance or, a reasoned statement of non-compliance or alternatively provide a statement of non-objection to prolong the period of regulatory data protection pursuant to this Article.** **4. In cases where a Member State has not replied to the application of the marketing authorisation holder within the deadline referred to in paragraph 3, it shall be considered hat a statement of non-objection has been provided. For medicinal products granted a centralised marketing authorisation the Commission shall vary the marketing authorisation pursuant to Article 47 of [revised Regulation (EC) No 726/2004] to prolong the data protection period. For medicinal products granted a marketing authorisation in accordance with the decentralised procedure, the competent authorities of the Member States shall vary the marketing authorisation pursuant to Article 92 to prolong the data protection period.** **5. Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Committee established by Council Decision 75/320/EEC 75 ('Pharmaceutical Committee'). The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.** **6. The Commission, based on the experience of Member States and relevant stakeholders, may adopt implementing**	

measures relating to the procedural aspects outlined in this Article and regarding the conditions mentioned in paragraph 1. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 214(2).	
Justification	
Proposed incentive for launch in all Member States concerned does focus on the end results – availability of medicines – but at the same time the extension of regulatory data protection applies only to approx. 30% of medicines (where the RDP is the last period of regulatory protection). CPME welcomes this attempt to improve availability of medicines, however we believe that an obligation for all marketing authorisation holders to file for pricing and reimbursement, in good faith, will result in broader coverage of medicines and will push manufacturers and the Member States to negotiate fair prices and ensure availability of medicines. Proposed obligation does not cover generic and biosimilar medicinal products. This amendment results in deleting provisions related to 24 months extension of regulatory data protection.	

Article 85

Text proposed by the Commission	**Amendment**
Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when **a reference medicinal product is used for the purposes of**: (a) studies, trials and other activities conducted **to generate data for an application,** for: (i) a marketing authorisation of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations; (ii) health technology assessment as defined in Regulation (EU) 2021/2282; (iii) pricing and reimbursement. (b) the activities **conducted exclusively for the purposes set out in point (a), may cover** the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers. This exception shall not cover the placing on the market of the medicinal products resulting from such activities	Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when: (a) studies, trials and other activities **are** conducted for **the purpose of**: (i) **Applying for** a marketing authorisation of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations; (ii) **Conducting** health technology assessment as defined in Regulation (EU) 2021/2282; (iii) **Filling for** pricing and reimbursement. **(iv) participating in a procurement to enable market entry of a generic or biosimilar product as soon as the relevant patents or supplementary protection certificates expire.** (b) the activities **falling under the first subparagraph include** the submission of the application for a marketing authorisation and the offer**ing, export**, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers. This exception shall not cover the placing on the market of the medicinal products resulting from such activities

Justification

All obstacles that prevent generic and biosimilar medicines from entering the market on the first day after the protection expires should be removed. This amendment proposes clarifications needed for the Bolar exemption to be effectively implemented. There should be no doubt about the application for authorization and filing for pricing and reimbursement, as well as conducting health technology assessment. Applying for supply is also needed to effectively achieve a day-one launch.

Article 177 – paragraph 1 – point (c) (new)

Text proposed by the Commission	**Amendment**
	(c) are antibiotics.
Justification	
This addition prohibits the advertising of antibiotics irrespective of their prescription status in line with the goals of reducing antimicrobial resistance and promoting the responsible use of these medicines.	

Article 177 – paragraph 2

Text proposed by the Commission	**Amendment**
2. Medicinal products may be advertised to the general public where, by virtue of their composition and purpose, they are intended and designed for use without the intervention of a ***medical practitioner*** for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist***, if necessary***.	2. Medicinal products may be advertised to the general public where, by virtue of their composition and purpose, they are intended and designed for use without the intervention of a ***healthcare professional*** for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist.
Justification	
Proper patient counselling is very important, especially in the case of non-prescription medicines. This is part of pharmacists' core professional activities as stipulated in the Professional Qualifications Directive (see Article 45(2)(g): "provision of information and advice on medicinal products as such, including on appropriate use"). Therefore, such advice is closely related to the patient's safe access to the medicinal product and, therefore, to the protection of public health in the Member States. As the CJEU has pointed out on several occasions, the role of pharmacist, and the guarantees they offer with regard to the information they provide to consumers through their advice is an element that minimises the risks to public health posed by the overconsumption or incorrect use of medicinal products (see e.g. Case C-531/06). Therefore, in order to ensure safe access to medicines, we suggest that pharmacist counselling should not be considered as optional. Furthermore, enlarging the scope from medical practitioners to healthcare professionals encompasses the natural development of health professions, where diagnosis and issuance of a prescription are actions that can be performed by a diverse array of health professions in line with a skills-mix approach.	

Article 177 – paragraph 4

Text proposed by the Commission	**Amendment**
4. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns ***carried out by the industry and*** approved by the competent authorities of the Member States.	4. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns approved by the competent authorities of the Member States.
Justification	
This proposed amendment removes the emphasis on the vaccination campaigns carried out by the industry. Vaccination campaigns are also carried out by other actors, including public authorities, health funds and healthcare professionals legally authorised to vaccinate in the different Member States.	

Article 185 – paragraph 1 – point (g)

Text proposed by the Commission	**Amendment**
(g) no samples of medicinal products containing substances classified as psychotropic or narcotic within the meaning of international conventions may be supplied.	(g) no samples of medicinal products containing substances classified as ***antibiotics for systemic use,*** psychotropic or narcotic within the meaning of international conventions may be supplied.
Justification	
This amendment removes the possibility to provide free samples of antibiotics for systemic use, in line with the goal of preventing antimicrobial resistance and contributing to raising awareness on this topic.	

Proposal for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency

Article 117 – paragraph 1

Text proposed by the Commission	**Amendment**
1. The marketing authorisation holder as defined in Article 116(1) shall have in place and keep up to date a shortage prevention plan, for any medicinal product placed on the market. To put in place the shortage prevention plan, the marketing authorisation holder shall include the minimum set of information set out in Part V of Annex IV and take into account the guidance drawn up by the Agency according to paragraph 2.	1. The marketing authorisation holder as defined in Article 116(1) shall have in place and keep up to date a shortage prevention plan, for any medicinal product placed on the market. To put in place the shortage prevention plan, the marketing authorisation holder shall include the minimum set of information set out in Part V of Annex IV and take into account the guidance drawn up by the Agency according to paragraph 2. ***The shortage prevention plan shall be made available to the Agency and the competent authority of the Member State where the medicinal product has been placed on the market.***
Justification	
The shortage prevention plan shall be made available to the Agency and National Competent Authorities to allow for its proper implementation and to allow for a proper and immediate assessment by authorities of the shortage mitigation plan in accordance with Article 118(2).	

Article 118 – paragraph 2

Text proposed by the Commission	**Amendment**
2. For the purposes of paragraph 1, the competent authority concerned as defined in Article 116(1) may request any additional information from the marketing authorisation holder as defined in Article 116(1). In particular, it may request the marketing authorisation holder to submit a shortage mitigation plan in accordance with Article 119(2), a risk assessment of impact of suspension, cessation or withdrawal in accordance with Article 119(3), or the shortage prevention plan referred to in Article 117. The competent authority concerned may set a deadline for the submission of the information requested.	2. For the purposes of paragraph 1, the competent authority concerned as defined in Article 116(1) may request any additional information from the marketing authorisation holder as defined in Article 116(1). In particular, it may request the marketing authorisation holder to submit ***updated versions of*** a shortage mitigation plan in accordance with Article 119(2), a risk assessment of impact of suspension, cessation or withdrawal in accordance with Article 119(3), or the shortage prevention plan referred to in Article 117. The competent authority concerned may set a deadline for the submission of the information requested.
Justification	
The shortage mitigation plan in accordance with Article 119(2), the risk assessment of impact of suspension, cessation or withdrawal in accordance with Article 119(3), and the shortage prevention plan referred to in Article 117 shall be in the possession of the competent authorities irrespective of whether or not the medicinal products are in shortage or in risk of shortage. As such, the competent authorities shall request updated versions for the purpose of shortage monitoring, as necessary.	

Article 121 – paragraph 1 – point (c a) (new)

Text proposed by the Commission	**Amendment**
	(c a) assess the information on potential or actual shortages provided by marketing authorisation holders authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public.
Justification	
National Competent authorities shall also be responsible for assessing the information received directly from marketing authorisation holders and information received from other supply chain stakeholders pursuant of Article 120(1).	

Article 130 – Paragraph 1

Text proposed by the Commission	**Amendment**
Role of the Agency 1. The Agency shall, in collaboration with the working party referred to in Article 121(1), point (c), ensure the following: (a) develop a common methodology to identify critical medicinal products, including the evaluation of vulnerabilities with respect to the supply chain of those medicines, in consultation**, where appropriate,** with relevant stakeholders;	Role of the Agency 1. The Agency shall, in collaboration with the working party referred to in Article 121(1), point (c), ensure the following: (a) develop a common methodology to identify critical medicinal products, including the evaluation of vulnerabilities with respect to the supply chain of those medicines, in consultation, with relevant stakeholders;
Justification	
Inclusion of HCPs and other relevant stakeholders in the development of a common methodology to identify critical medicinal products cannot be optional. Methodology should be transparent and elaborated in a collaborative way.	

Article 143 – paragraph 1

Text proposed by the Commission	**Amendment**
1. The Management Board shall be composed of one representative from each Member State, two representatives of the Commission and two representatives of the European Parliament, all with voting rights. In addition, two representatives of patients' organisations, one representative of doctors' organisations and one representative of veterinarians' organisations, all with voting rights, shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes appreciably more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible, and at the latest within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint these representatives to the Management Board. The members of the Management Board shall be appointed in such a way as to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise and the broadest possible geographic spread within the European Union.	1. The Management Board shall be composed of one representative from each Member State, two representatives of the Commission and two representatives of the European Parliament, all with voting rights. In addition, two representatives of patients' organisations, one representative of *doctors'* organisations***, one representative of pharmacists'*** **organisations,** and one representative of veterinarians' organisations, all with voting rights, shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes appreciably more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible, and at the latest within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint these representatives to the Management Board. The members of the Management Board shall be appointed in such a way as to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise and the broadest possible geographic spread within the European Union.
Justification	
The proposal limits the presence of health professionals on the Management Board to doctors and veterinarians (i.e., the respective prescribers of medicinal products for human and veterinary use), but does not include pharmacists. Pharmacists are health professional with specific expertise in medicinal products and, in most Member States, the only professional authorised to dispense such products to the public (e.g. the EU Professional Qualifications Directive refers to them as 'specialises in the field of medicinal products' and requires their training to encompass knowledge of medicinal products and the substances used in their manufacture). We therefore consider it essential to allow for a representative of pharmacists' organisations to be present on the Management Board, in order to further expand the scope of input and information that these professionals can contribute to the discussions, being essential that not only the prescribing professionals but also the dispensers' point of view is present.	